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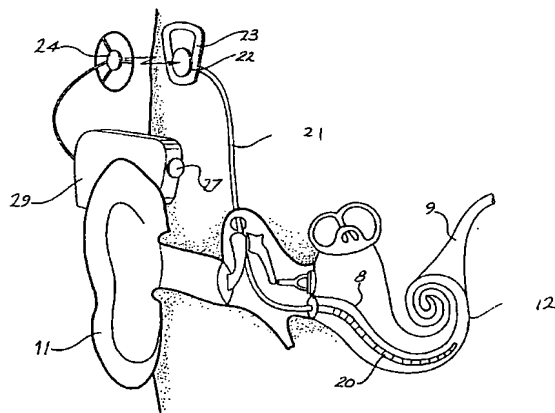
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(54) Title: CURVED COCHLEAR IMPLANT ELECTRODE ARRAY



(57) Abstract: An implantable electrode array (30) that can adopt a first, preferably straight, configuration selected to allow the array to be inserted into an implantee's body, such as the cochlea, and at least a second, preferably spirally curved, configuration where the electrode array is adapted to apply tissue stimulation to the cochlea. The array (30) includes an elongate carrier (31) having a proximal end and a distal end and a plurality of electrodes (36) supported by the carrier (31) at respective longitudinally spaced locations thereon. The array (30) further comprises an outer layer (33) adhered to the elongate carrier (31) by an intermediate bioresorbable adhesive layer (32) positioned at least partially between the carrier (31) and the outer layer (33). The outer layer (33) is shaped so as to normally preferentially adopt the second configuration, while the bioresorbable adhesive layer (32) has a configuration selected for biasing the array (30) into the first configuration prior to insertion of the array (30) into the cochlea. A method of forming the array (30) is also disclosed.

## **"Curved cochlear implant electrode array"**

### Field of the Invention

5           The present invention relates to an implantable device and, in particular, to an implantable cochlear electrode assembly. A method of manufacturing such a device is also described.

### Background of the Invention

10

Hearing loss, which may be due to many different causes, is generally of two types, conductive and sensorineural. Of these, conductive hearing loss occurs where the normal mechanical pathways for sound to reach the hair cells in the cochlea are impeded, for example, by damage to the ossicles.

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Conductive hearing loss may often be helped by use of conventional hearing aids, which amplify sound so that acoustic information does reach the cochlea and the hair cells.

20

In many people who are profoundly deaf, however, the reason for their deafness is sensorineural hearing loss. This type of hearing loss is due to the absence of, or destruction of, the hair cells in the cochlea which transduce acoustic signals into nerve impulses. These people are thus unable to derive suitable benefit from conventional hearing aid systems, no matter how loud the acoustic stimulus is made, because there is damage to or absence of the mechanism for nerve impulses to be generated from sound in the normal manner.

25

It is for this purpose that cochlear implant systems have been developed. Such systems bypass the hair cells in the cochlea and directly deliver electrical stimulation to the auditory nerve fibres, thereby allowing the brain to perceive a hearing sensation resembling the natural hearing sensation normally delivered to the auditory nerve. US Patent 4532930, the contents of which are incorporated herein by reference, provides a description of one type of traditional cochlear implant system.

30

35

Typically, cochlear implant systems have consisted of essentially two components, an external component commonly referred to as a processor unit and an internal implanted component commonly referred to as a stimulator/receiver unit. Traditionally, both of these components have  
5 cooperated together to provide the sound sensation to a user.

The external component has traditionally consisted of a microphone for detecting sounds, such as speech and environmental sounds, a speech processor that converts speech into a coded signal, a power source such as a  
10 battery, and an external transmitter coil.

The coded signal output by the sound processor is transmitted transcutaneously to the implanted stimulator/receiver unit situated within a recess of the temporal bone of the user. This transcutaneous transmission  
15 occurs via the external transmitter coil which is positioned to communicate with an implanted receiver coil provided with the stimulator/receiver unit. This communication serves two essential purposes, firstly to transcutaneously transmit the coded sound signal and secondly to provide power to the implanted stimulator/receiver unit. Conventionally, this link has been in the  
20 form of a radio frequency (RF) link, but other such links have been proposed and implemented with varying degrees of success.

The implanted stimulator/receiver unit traditionally includes a receiver coil that receives the coded signal and power from the external processor  
25 component, and a stimulator that processes the coded signal and outputs a stimulation signal to an intracochlea electrode assembly which applies the electrical stimulation directly to the auditory nerve producing a hearing sensation corresponding to the original detected sound.

Traditionally, the speech processor of the external componentry has  
30 been carried on the body of the user, such as in a pocket of the user's clothing, a belt pouch or in a harness, while the microphone has been mounted on a clip mounted behind the ear or on the lapel of the user.

More recently, due in the main to improvements in technology, the  
35 physical dimensions of the sound processor have been able to be reduced

allowing for the external componentry to be housed in a small unit capable of being worn behind the ear of the user. This unit allows the microphone, power unit and the sound processor to be housed in a single unit capable of being discretely worn behind the ear, with the external transmitter coil still positioned  
5 on the side of the user's head to allow for the transmission of the coded sound signal from the sound processor and power to the implanted stimulator unit.

It is known in the art that the cochlea is tonotopically mapped. In other words, the cochlea can be partitioned into regions, with each region being  
10 responsive to signals in a particular frequency range. This property of the cochlea is exploited by providing the electrode assembly with an array of electrodes, each electrode being arranged and constructed to deliver a stimulating signal within a preselected frequency range to the appropriate cochlea region. The electrical currents and electric fields from each electrode  
15 stimulate the nerves disposed on the modiolus of the cochlea.

It has been found that in order for these electrodes to be effective, the magnitude of the currents flowing from these electrodes and the intensity of the corresponding electric fields, are a function of the distance between the  
20 electrodes and the modiolus. If this distance is relatively great, the threshold current magnitude must be larger than if the distance is relatively small. Moreover, the current from each electrode may flow in all directions, and the electrical fields corresponding to adjacent electrodes may overlap, thereby causing cross-electrode interference. In order to reduce the threshold  
25 stimulation amplitude and to eliminate cross-electrode interference, it is advisable to keep the distance between the electrode array and the modiolus as small as possible. This is best accomplished by providing the electrode array in a shape which generally follows the shape of the modiolus. Also, this way the delivery of the electrical stimulation to the auditory nerve is most  
30 effective as the electrode contacts are as close to the auditory nerves that are particularly responsive to selected pitches of sound waves.

In order to achieve this electrode array position close to the inside wall of the cochlea, the electrode assembly can be designed such that it assumes this  
35 position upon or immediately following insertion into the cochlea. This is a challenge as the assembly needs to be shaped such that it assumes a curved

shape to conform with the shape of the modiolus and must also be shaped such that the insertion process causes minimal trauma to the sensitive structures of the cochlea. In this regard, it has been found to be desirable that the electrode assembly be generally straight during the insertion procedure.

5

Several procedures have been adopted to provide an electrode assembly that is relatively straight during initial insertion while adopting a curved configuration following insertion in the cochlea. In one case, a platinum wire stylet is used to hold a pre-curved electrode assembly in a generally straight configuration up until insertion. The platinum wire is inserted into a lumen or channel located in the pre-curved electrode assembly with such lumen/channel allowing a passageway to accommodate the stylet. During or immediately following insertion, the platinum stylet is withdrawn allowing the assembly to return to its pre-curved configuration.

15

The present invention is directed to an electrode assembly that can preferably be inserted more deeply into the cochlea whilst also preferably reducing the degree of trauma to the sensitive structures within the cochlea. A method of manufacturing such an electrode assembly is also described.

20

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the purpose of providing a context for the present invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed in Australia before the priority date of each claim of this application.

25

#### Summary of the Invention

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Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

35

According to a first aspect, the present invention is an implantable electrode array that can adopt a first configuration selected to allow the array to be inserted into an implantee's body and at least a second configuration wherein said electrode array is adapted to apply tissue stimulation, the array  
5 including an elongate carrier having a proximal end and a distal end, a plurality of electrodes supported by the carrier at respective longitudinally spaced locations thereon in a region between the proximal end and the distal end, and an outer layer adhered to the elongate carrier by an intermediate bioresorbable adhesive layer positioned at least partially between the carrier and the outer  
10 layer, the outer layer being shaped so as to normally preferentially adopt the second configuration, the bioresorbable adhesive layer having a configuration selected for biasing the array into said first configuration prior to insertion of the array into the implantee's body.

15 In a preferred embodiment, the implantable electrode array is a cochlear implant electrode array that is adapted for insertion into the cochlea of an implantee. Preferably, the array is adapted for insertion into the scala tympani of the cochlea of the implantee.

20 In a further embodiment, the elongate carrier has an inner surface designed to conform, following implantation, substantially with the inner wall of the cochlea.

In a still further embodiment, at least one of the electrodes has a surface  
25 that is at least adjacent the inner surface of the carrier. More preferably, each of the electrodes in the array has a surface that is adjacent the inner surface of the carrier. In a further embodiment, the surfaces of the electrodes are aligned with the inner surface of the carrier. In another embodiment, the surfaces of the electrodes stand proud of the inner surface of the carrier. It is also  
30 envisaged that the electrode surface could also be recessed into the inner surface of the carrier.

In another embodiment, the outer layer can have a length such that it extends from the proximal end to the distal end of the carrier. In another  
35 embodiment, the outer layer may have a length longer than the distance between the proximal end and distal end of the carrier. It is also envisaged that

the outer layer could have a length shorter than the distance between the proximal end and distal end of the carrier.

While the array could incorporate additional layers than that defined  
5 above, for simplicity, the invention will mainly be described below as consisting only of the carrier, the outer layer and the intermediate adhesive layer.

In one embodiment, the outer layer can be formed from a material  
different to that of the carrier. In another embodiment, the carrier and outer  
10 layer can be formed from the same material. In this latter case, the carrier and outer layer can have different mechanical properties despite being formed of the same material.

In one embodiment, the carrier and the outer layer can be formed from a  
15 biocompatible elastomeric material. In one embodiment, the elastomeric material can be a silicone rubber. In one embodiment, the biocompatible material can be a silicone, such as a flexible silicone elastomer-Silastic. Silastic MDX 4-4210 is an example of one suitable silicone for use in the formation of the elongate member. In another embodiment, the elongate  
20 carrier and/or outer layer can be formed from a biocompatible polyurethane or similar material.

In a further embodiment, the thickness of the carrier between its inner surface and outer surface can be substantially constant for at least a majority of  
25 its length from the proximal end to the distal end. In another embodiment, the thickness of the carrier can change, such as decrease, from the proximal end to the distal end. In a preferred embodiment, the carrier can be relatively more resiliently flexible in a longitudinal plane and relatively less resiliently flexible in a lateral plane. In one embodiment, the carrier can have an oval-shaped cross-  
30 section and is preferably relatively more flexible in the direction of curvature of the cochlea and relatively stiffer in other planes.

In a further embodiment, the thickness of the outer layer can be constant for at least a majority of its length. In a still further embodiment, the thickness  
35 of the outer layer can change, such as decrease, from its proximal end to its distal end.

In a still further embodiment, the thickness of the outer layer can be substantially the same as the carrier. It can, however, be envisaged that the thickness of the outer layer may be greater than or less than the thickness of the carrier.

In a preferred embodiment, the carrier is preferably relatively resiliently flexible such that it adopts the first configuration of the array determined by the adhesive layer prior to implantation and the second, preferably spirally curved, configuration determined by the preferred configuration of the outer layer following completion of the implantation procedure.

Preferably, the curved configuration of the array following completion of implantation is such that the carrier can fit inside the cochlea of the implantee with said adjacent surfaces of the electrodes being oriented to face the modiolus of the cochlea.

The outer surface of the outer layer of the array is preferably smooth to prevent any damage to the cochlea as the array is inserted into the cochlea.

The adhesive layer is formed from a bioresorbable material that softens or dissolves on exposure to a fluid. The adhesive layer preferably softens or dissolves on exposure to a saline solution or a body fluid of the implantee, such as cochlear fluid. As the adhesive layer softens, it preferably becomes lubricious allowing the outer layer to begin to adopt its normal preferential curved configuration. It will be appreciated that due to the constraints imposed by the geometry of the cochlea and/or the presence of the carrier within the cochlea, the array and the outer layer may not adopt a curved configuration identical to that that can be adopted by the outer layer prior to it being adhered to the carrier. In one embodiment, the outer layer, prior to being adhered to the carrier, preferably subtends an angle of between one and a half to two turns, or of about 540 - 720°. Following implantation, the carrier preferably subtends an angle of at least about 360° and more preferably about 450°.

In a further embodiment, the bioresorbable material of the adhesive layer is selected from the group consisting of polyacrylic acid (PAA), polyvinyl alcohol



(PVA), polylactic acid (PLA) and polyglycolic acid (PGA). It is envisaged that other similar materials could also be used.

In one embodiment, at least a portion of the carrier may be attached to at least a portion of the outer layer by a means other than said adhesive layer. For example, the distal end of the carrier may be attached to the distal end of the outer layer. More than one such attachment may exist between the carrier and the outer layer. The attachment may be provided by a non-bioresorbable adhesive. In another embodiment, the attachment may comprise an integral connection between the carrier and outer layer. Still further, the attachment may be a disengageable attachment.

In a preferred embodiment, the electrode array can include electrically conducting wires connected to the electrodes and extending to at least said proximal end. In one embodiment, one wire can be connected to each of said electrodes. In another embodiment, at least two wires can be connected to each of said electrodes.

Each electrode can comprise a contact element. The carrier can have a longitudinal axis with each contact element arranged orthogonally to the longitudinal axis. The contact elements can be formed from a biocompatible material. The biocompatible material of the contact element can be platinum. The wires are preferably connected to the contact elements by welding.

Once implanted, the electrodes of the carrier member preferably receive stimulation signals from a stimulator means. The stimulator means is preferably electrically connected to the elongate carrier member by way of an electrical lead. The lead can include the one or more wires extending from each electrode of the array mounted on the elongate member.

In one embodiment, the lead can extend from the elongate member to the stimulator means or at least the housing thereof. In one embodiment, the lead is continuous with no electrical connectors, at least external the housing of the stimulator means, required to connect the wires extending from the electrodes to the stimulator means. One advantage of this arrangement is that there is no requirement for the surgeon implanting the device to make the

necessary electrical connection between the wires extending from the electrodes and the stimulator means.

The stimulator means is preferably positioned within a housing that is  
5 implantable within the implantee. The housing for the stimulator means is preferably implantable within a recess in the bone behind the ear posterior to the mastoid.

When implanted, the housing preferably contains, in addition to the  
10 stimulator means, a receiver means. The receiver means is preferably adapted to receive signals from a controller means. The controller means is, in use, preferably mounted external to the body of the implantee such that the signals are transmitted transcutaneously through the skin of the implantee.

15 Signals can preferably travel from the controller means to the receiver means and vice versa. The receiver means can include a receiver coil adapted to receive radio frequency (RF) signals from a corresponding transmitter coil worn externally of the body. The radio frequency signals can comprise frequency modulated (FM) signals. While described as a receiver coil, the  
20 receiver coil can preferably transmit signals to the transmitter coil which receives the signals.

The transmitter coil is preferably held in position adjacent the implanted location of the receiver coil by way of respective attractive magnets mounted  
25 centrally in, or at some other position relative to, the coils.

The external controller can comprise a speech processor adapted to receive signals output by a microphone. During use, the microphone is preferably worn on the pinna of the implantee, however, other suitable locations  
30 can be envisaged, such as a lapel of the implantee's clothing. The speech processor encodes the sound detected by the microphone into a sequence of electrical stimuli following given algorithms, such as algorithms already developed for cochlear implant systems. The encoded sequence is transferred to the implanted stimulator/receiver means using the transmitter and receiver  
35 coils. The implanted stimulator/receiver means demodulates the FM signals

and allocates the electrical pulses to the appropriate attached electrode by an algorithm which is consistent with the chosen speech coding strategy.

5 The external controller further comprises a power supply. The power supply can comprise one or more rechargeable batteries. The transmitter and receiver coils are used to provide power via transcutaneous induction to the implanted stimulator/receiver means and the electrode array.

10 While the implant system can rely on external componentry, in another embodiment, the controller means, including the microphone, speech processor and power supply can also be implantable. In this embodiment, the controller means can be contained within a hermetically sealed housing or the housing used for the stimulator means.

15 In yet a further embodiment, a longitudinal lumen can extend through the carrier and/or the outer layer for at least a portion of their respective lengths. The lumen can act as a substance delivery means for delivering a bio-active substance to the implant site following implantation.

20 The lumen can act as a reservoir for the bio-active substance. In one embodiment, the bio-active substance in the reservoir can leach from the lumen into the surrounding material of the carrier or outer layer and eventually migrate out of the array to the desired site of action for the bio-active substance. In another embodiment, the carrier and/or outer layer can have one  
25 or more substance egress means whereby the bio-active substance can move out of the lumen and through the carrier and/or outer layer to a position that is preferably close to the desired site of action for the bio-active substance.

30 Where the bio-active substance is carried in or comprises a fluid, each substance egress means preferably comprises a fluid egress means.

Each fluid egress means preferably has a valve means that allows fluid to exit the lumen but prevents, or at least substantially prevents, fluid flow from external the elongate member back into the lumen.

In a further embodiment, the proximal opening of the lumen can be in fluid communication with an additional reservoir for the bio-active substance that is external to the array. A pumping means, such as an osmotic pump, can transfer the bio-active substance from the additional reservoir into the lumen for subsequent delivery to the appropriate site of action.

It is also envisaged that the bio-active substance can be captured in the form of a solid pellet. An example of how this may occur is by impregnating the bio-active substance in a ceramic or a polymer pellet that has a predetermined rate of release of the bioactive substance. This solid pellet can then be stored in the lumen reservoir or in an external reservoir connectable to the lumen.

In one embodiment, the bioactive substance can comprise a steroid. In another embodiment, the bioactive substance can perform a function of reducing the resting neuron potential of neurons within the cochlea. The use of such substances can result in less energy being required to excite the neurons and cause stimulation. In yet another embodiment, the bioactive substance can comprise a nerve growth factor and mimetics to enhance the survival and growth of the nerve cells in the cochlea to improve the performance of the cochlear implant.

In a still further embodiment, at least a portion of the surface of the carrier can have a coating of lubricious material. In a further embodiment, a substantial portion of the surface can have a coating of the lubricious material.

The lubricious material preferably becomes lubricious on being brought into contact with a fluid, such as a saline solution. Still further, the coating preferably becomes lubricious on being brought into contact with a body fluid, such as cochlear fluid.

In one embodiment, the lubricious material is selected from the group consisting of polyacrylic acid (PAA), polyvinyl alcohol (PVA), polylactic acid (PLA) and polyglycolic acid (PGA). It is envisaged that other similar materials could also be used. It is envisaged that the lubricious material can also be impregnated with the bio-active substance allowing the coating to perform a

dual role. The rate of delivery of the bio-active substance can be programmed by design of the coating structure.

5 In a still further embodiment, the array can be enveloped by a stiffening sheath which is made of a material that is relatively stiffer than the resiliently flexible material of the carrier. The stiffening sheath can be adapted to assist in biasing the array into at least a substantially straight configuration prior to implantation. In one embodiment, the stiffening sheath can be overlaid by the coating of lubricious material.

10

The stiffening sheath, if present, can be formed of a bioresorbable material which dissolves or softens on exposure to a fluid. The stiffening sheath can dissolve or soften on exposure to a saline solution or a body fluid of the implantee, such as cochlear fluid, and in doing so also release one or more  
15 bio-active substances impregnated therein.

In a further embodiment, the bioresorbable material of the stiffening sheath is selected from the group consisting of polyacrylic acid (PAA), polyvinyl alcohol (PVA), polylactic acid (PLA) and polyglycolic acid (PGA). It is also  
20 envisaged that other suitable materials could also be used. It is envisaged that the bioresorbable element of the stiffening sheath can also be impregnated with one or more bio-active substances allowing the stiffening sheath to perform a dual role. The rate of delivery of the bio-active substance can be programmed by design of the sheath structure.

25

The array can still further include an additional layer surrounding the stiffening sheath. The additional layer can have a first rate of fluid ingress therethrough and have at least one fluid ingress means formed therein, the rate of fluid ingress through the fluid ingress means being greater than the first rate  
30 of fluid ingress through the additional layer. In this embodiment, the coating of lubricious material can be coated on the outside of the additional layer.

The fluid ingress means can comprise one or more openings in the additional layer. The openings can be closable. The openings can comprise  
35 slits in the additional layer. The slits can be formed to allow substantially the same or the same rate of ingress of fluid through the additional layer. In

another embodiment, at least one slit can allow a different rate of progress of fluid through the additional layer compared to the other slits.

5 The stiffening sheath, if present, can be formed from a shape memory or heat sensitive material. For example, the stiffening sheath can be formed from a bimetallic filament (such as nickel/titanium) and shaped to take and maintain the straight or substantially straight configuration of the array at room temperature but bend it into another shape once it is exposed to body temperature.

10

The present invention provides a surgeon with a cochlear implant electrode array that can potentially be inserted to a greater depth than hitherto known electrode arrays whilst maintaining close proximity between the surfaces of the electrodes and the modiolus. The present invention does not require the addition of cochlea space-filling positioner devices to achieve this greater depth and as such the surgery required is much less invasive than that required when inserting cochlea space-filling devices. In particular, by removing the need to withdraw a stylet or other stiffening member from the array during implantation, the surgeon is provided with a more straightforward means of achieving successful implantation of the array.

20 According to a further aspect, the present invention is a method of manufacturing an implantable electrode array that can adopt a first configuration selected to allow the array to be inserted into an implantee's body and at least a second configuration wherein said electrode array is adapted to apply tissue stimulation, the method including the steps of:

(i) moulding an elongate carrier in a substantially straight configuration in a first mould from a resiliently flexible material about a longitudinal array of electrodes such that at least one of the electrodes has a surface that is at least adjacent an inner surface of the carrier;

30 (ii) separately moulding at least an outer layer of the array in a second mould from a resiliently flexible material, the outer layer being moulded in a curved configuration;

(iii) removing the outer layer from the second mould, straightening the outer layer and adhering it to the carrier using a bioresorbable adhesive.

35

The carrier can be formed about a longitudinal array of electrodes such that at least one of the electrodes has a surface that is at least adjacent an inner surface of the carrier.

5 In a preferred embodiment, the electrodes can comprise a plurality of contact elements. The formed carrier can have a longitudinal axis with each electrode arranged orthogonally to the longitudinal axis. The electrodes can be formed from a biocompatible material, such as platinum. The electrode array is preferably formed by positioning a series of platinum contact members in a  
10 production jig.

Once positioned, a series of electrically conducting wires can be welded to each of the electrodes. Each electrode preferably has at least one, and possibly two, electrically conducting wire welded thereto. Connecting the  
15 electrodes to multiple wires provides redundancy in case one of the wires breaks, and also provides greater mechanical flexibility for a given electrical resistance.

Once the electrodes are positioned within the production jig and  
20 connected to the electrically conducting wires, the electrodes are placed in the first mould to allow moulding of the carrier.

In a preferred embodiment, the array is adapted for insertion into the cochlea. As such, it is preferred that the array, once implanted, will adopt a  
25 configuration that substantially matches the spiral configuration of the cochlea. To assist the array in forming a spiral configuration following implantation, the array includes the outer layer. The second mould used to mould the outer layer is preferably spiral-shaped such that the outer layer, following its manufacture and removal from the second mould, preferably subtends an arc of greater than  
30 450° once formed. The mould is preferably specifically adapted to form an outer or outer layer having a spiral shape that subtends an arc greater than that will be subtended by the array following completion of the implantation procedure. This is achieved by designing the mould so that the radius of each turn is reduced over the length of the mould, so that a tight curvature of the  
35 outer layer is achieved.

The carrier is preferably formed from an elastomeric silicone material and remains in the first mould at least until completion of curing. The outer layer is also preferably formed from an elastomeric silicone material. The outer layer can be formed from the same material as the carrier or a different material.

Once the outer layer is cured, it can be removed from the second mould and straightened. The outer layer may be straightened by and held straight in a straightening jig. Preferably the outer layer is moulded in a tighter curvature than the cochlea, such that when the carrier with the rings and wires is in contact with the outer layer, the entire configuration conforms with the curvature of the cochlea.

Once at least substantially straightened, the outer layer can then be adhered to the top of the cured carrier that is still in the first mould. The straightened outer layer is adhered to the carrier via an intermediate adhesive layer.

Once the outer layer is adhered to the carrier, the array formed by this process can be removed from the first mould. The adhesive layer used to bond the carrier and outer layer retains the array in a straight or substantially straight configuration despite the propensity of the outer layer to want to return to its moulded spiral shape.

According to a third aspect, the present invention is a method of inserting an implantable electrode array in a cochlea of an implantee comprising the steps of:

- (i) performing a cochleostomy;
- (ii) inserting the electrode array as defined herein through the cochleostomy;
- (iii) closing the cochleostomy.

During step (ii), the adhesive layer bonding the outer layer and carrier preferably gradually dissolves thereby allowing the outer layer to begin to move towards its second configuration and so pushing the resiliently flexible carrier closer to the inner wall of the cochlea.



During insertion into the cochlea, the array would conform to the outer wall. The surgeon would cease insertion once the array has been inserted to an appropriate depth, which may be indicated by a depth marker on the array.

5 As the array is exposed to cochlear fluid, the adhesive layer bonding the outer layer and carrier would begin to gradually dissolve. The rate of dissolution would be dependent on factors such as the degree of exposure of the adhesive layer to the cochlear fluid.

10 As the adhesive layer softens and becomes more lubricious, the outer layer gradually begins to move towards its natural curved configuration. As it curves, the outer layer pushes on the resiliently flexible carrier bringing it closer to the inner wall of the cochlea. The degree of curvature of the outer layer is preferably such that the final resting position of the carrier is against the  
15 modiolus but without exerting any or excessive pressure on the modiolus.

#### Brief Description of the Drawings

By way of example only, a preferred embodiment of the invention is now  
20 described with reference to the accompanying drawings, in which:

Fig. 1 is a pictorial representation of a prior art cochlear implant system;

Fig. 2 is a simplified longitudinal sectional view of a cochlear electrode  
25 array according to the present invention in its pre-insertion state;

Fig. 3 is a sectional view taken along line 3-3 of Fig. 2;

Figs. 4, 5 and 6 are simplified schematic illustrations of the initial,  
30 intermediate and final stages of the insertion of a cochlear electrode array into the cochlea of a human being; and

Fig. 7 is a plan view of a second mould according to the present invention for forming an outer layer as defined herein.

### Preferred Mode of Carrying out the Invention

Before describing the features of the present invention, it is appropriate to briefly describe the construction of one type of known cochlear implant system with reference to Fig. 1.

Known cochlear implants typically consist of two main components, an external component including a speech processor 29, and an internal component including an implanted receiver and stimulator unit 22. The external component includes a microphone 27. The speech processor 29 is, in this illustration, constructed and arranged so that it can fit behind the outer ear 11. Alternative versions may be worn on the body. Attached to the speech processor 29 is a transmitter coil 24 that transmits electrical signals to the implanted unit 22 via a radio frequency (RF) link.

The implanted component includes a receiver coil 23 for receiving power and data from the transmitter coil 24. A cable 21 extends from the implanted receiver and stimulator unit 22 to the cochlea 12 and terminates in an electrode array 20. The signals thus received are applied by the array 20 to the basilar membrane 8 and the nerve cells within the cochlea 12 thereby stimulating the auditory nerve 9. The operation of such a device is described, for example, in US patent No. 4532930.

As depicted diagrammatically in Fig. 1, the cochlear implant electrode array 20 has traditionally been inserted into the initial portion of the scala tympani of the cochlea 12 up to about a full turn within the cochlea. The electrode array according to the present invention is adapted to be inserted more deeply into the cochlea 12 than has historically been the case.

One embodiment of a cochlear implant electrode array, according to the present invention, is depicted generally as 30 in the remaining drawings.

The array 30 comprises an elongate electrode carrier member 31 of substantially oval cross-section, an intermediate adhesive layer 32, and an outer layer 33. The depicted carrier member 31 and outer layer 33 are each moulded from a suitable biocompatible resiliently flexible silicone. In the

depicted embodiments, each layer 31,33 is formed from the same elastomeric silicone material. It will be understood by a person skilled in the art that the layers 31,33 could be formed from different materials to one another should a particular characteristic of the material be desired.

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Following its manufacture, the array 30 is maintained in a substantially straight or straight configuration ready for insertion in the scala tympani of a human cochlea 12.

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While the depicted array 30 normally adopts a substantially straight or straight configuration, following manufacture, it will be appreciated that the array 30 could be manufactured to adopt another configuration following manufacture.

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The carrier member 31 has a first distal end 34 that is firstly inserted into the cochlea 12 upon insertion of the array 30. The carrier member also has an inner surface 35 adapted to be positioned at least close to the surface of the modiolus of the cochlea 12 following insertion of the array 30. Disposed along the carrier member 31 are a plurality of electrodes 36. It will be appreciated that the electrodes 36 depicted in the drawings are not necessarily drawn to scale. Further, more or less electrodes 36 than that depicted in the drawings could be utilised in the carrier member 31. Each electrode 36 comprises a platinum contact surface having an outer surface at least adjacent, and preferably substantially aligned with, the inner surface 35 of the carrier member 31. At least one electrically conducting wire 40 extends from each of the electrodes 36 through the elongate member 31 to at least the proximal end 37 of the carrier member 31. The wires 40 extend back to an implanted stimulator/receiver unit, such as unit 22 depicted in Fig. 1.

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The depicted adhesive layer 32 is formed from a bioresorbable material that softens or dissolves on exposure to cochlear fluid. As the adhesive layer 32 softens, it preferably becomes lubricious allowing the outer layer 33 to begin to attempt to adopt its normal preferential curved configuration. It will, however, be appreciated that due to the constraints imposed by the geometry of the cochlea 12 and/or the presence of the carrier 31 within the cochlea 12, the carrier 31 and the outer layer 33 may not adopt a curved configuration identical

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to that that can be adopted by the outer layer 33 prior to it being adhered to the carrier 31. However, due to the fact that the outer layer 33 can move in relation to the carrier 31, and "slip" across the surface of the carrier 31, especially in the presence of the lubricious material, there will be a considerable increase in the amount of curvature possible if the two layers were in full contact along their surfaces.

In one embodiment, the outer layer 33, prior to being adhered to the carrier 31, subtends an angle at least greater than about 450°. Following implantation, the carrier 31 preferably subtends an angle of at least about 360°.

In the depicted embodiment, the bioresorbable material of the adhesive layer 32 is selected from the group consisting of polyacrylic acid (PAA), polyvinyl alcohol (PVA), polylactic acid (PLA) and polyglycolic acid (PGA). It is envisaged that other similar materials could also be used.

In the depicted embodiment, the distal end 34 of the carrier 31 is attached to a distal end 41 of the outer layer by a non-bioresorbable adhesive 42. A similar attachment is also provided between the proximal end 43 of the outer layer 33 and the carrier 31. More than two such attachments may also exist between the carrier 31 and the outer layer 33.

The bioresorbable material of the adhesive layer 32 has a sufficient stiffness to retain the silicone elongate carrier member 31 in a straight configuration.

The array 30 is typically delivered to a surgeon in a sterile package. On removal from the package, the array 30 is inserted into the scala tympani of the cochlea 12 as is depicted in Fig. 4, with the inner surface 35 of the carrier 31 directed towards the inner wall 44 of the cochlea 12. Due to the resilient nature of the array 30, as the surgeon pushes the array in the direction of arrow A, the carrier 31 and the outer layer 33 of the array 30 are inserted together as one unit due to the presence of the adhesive layer 32 and/or the non-bioresorbable adhesive 42.

As the insertion continues, the array 30 enters the spirally curved section of the cochlea 12, with the outer surface of the outer layer 33 gliding gently along the radially outer wall 45 of the cochlea 12 (Fig. 5). As insertion continues it is possible for the adhesive layer to begin to dissolve thereby causing the array 30 to assume a shape that assists the insertion process. This would be due to the natural curvature of the outer layer 33 forcing the carrier member 31 into a curved configuration and towards the inner wall 44 of the cochlea 12, with the result that the electrodes 36 facing the modiolus within the cochlea 12 are positioned as close as possible to the spiral ganglia 46 thereof (see Fig. 6). It is also considered that due to the resilient nature of the array 30, the array could also be inserted without the need for the dissolution process to take place during the insertion procedure, providing an array that is inserted in the same manner as the existing arrays.

The design of the cochlear implant electrode array 30 allows the elongate carrier member 31 to be inserted, in a typical case, more deeply into the scala tympani of the cochlea 12 than would be the case for hitherto traditionally used arrays, such as array 20 depicted in Fig. 1. The design of the array 30 also allows for the insertion process to be greatly simplified whilst allowing improved positioning of the electrode contact members 36 proximal to the inner wall of the cochlear. This is done by designing the array to naturally assume the final position without the need for additional activity from the surgeon such as the removal of a stylet or the introduction of a space filling positioning member to force the array into contact with the inner wall. In the current invention, following insertion of the array to the desired depth, the natural dissolution of the intermediate bioresorbable adhesive layer allows the naturally curved outer layer to gently bring the carrier into close proximity to the inner wall of the cochlea. There is no need, therefore, for complicated and potentially damaging techniques or devices to finally force the array into position.

To form the depicted electrode array 30, a plurality of platinum contact members, which become the electrodes 36, are mounted in a jig. Each contact member 36 has one, and possibly two, conductive wires welded thereto to allow electrical connection from the implanted stimulator/receiver unit 22 to the contact members 36.

Once formed, the electrode assembly is placed in a first straight mould, with the outer surfaces of the contact members 36 abutting the inner surface thereof. Once correctly positioned in the first mould, a silicone is poured or  
5 injected into the first mould around the electrode configuration and allowed to cure.

Meanwhile, the outer layer is formed in a second mould, such as the spiral-shaped channel 51 of second mould 50 depicted in Fig. 7. Once the  
10 outer layer 33 is positioned in the second mould 50, a further quantity of silicone can be poured or injected into the mould and allowed to cure, if desired. Once cured, the formed elastomeric outer layer 33 can be removed from the second mould 50. The outer layer 33, on removal from the second mould 50, naturally adopts the curved configuration of the mould 50.

15 Once removed from the second mould 50, the outer layer 33 is straightened and adhered, using adhesive layer 32, to the carrier member that is still in position in its mould.

20 Once the outer layer 33 has adhered to the carrier member 31, the array 30 can be removed from the first mould.

The use of the process as defined herein results in the formation of a straight electrode array 30 that will begin to adopt a curved configuration  
25 following implantation.

While the preferred embodiment of the invention has been described in conjunction with a cochlear implant, it is to be understood that the present invention has wider application to other implantable electrodes, such as  
30 electrodes used with pacemakers.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention  
35 as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

## CLAIMS:

1. An implantable electrode array that can adopt a first configuration selected to allow the array to be inserted into an implantee's body and at least  
5 a second configuration wherein said electrode array is adapted to apply tissue stimulation, the array comprising an elongate carrier having a proximal end and a distal end, a plurality of electrodes supported by the carrier at respective longitudinally spaced locations thereon in a region between the proximal end and the distal end, and an outer layer adhered to the elongate carrier by an  
10 intermediate bioresorbable adhesive layer positioned at least partially between the carrier and the outer layer, the outer layer being formed so as to normally preferentially adopt the second configuration, the bioresorbable adhesive layer having a configuration selected for biasing the array into said first configuration prior to insertion of the array into the implantee's body.
- 15 2. An implantable electrode array of claim 1 wherein the implantable electrode array is a cochlear implant electrode array insertable into the cochlea of an implantee.
- 20 3. An implantable electrode array of claim 2 wherein the elongate carrier has an inner surface that is substantially conformable, following implantation, with the inner wall of the cochlea.
4. An implantable electrode array of claim 3 wherein each of the electrodes  
25 in the array have a surface that is at least adjacent the inner surface of the carrier.
5. An implantable electrode array of claim 2 wherein the outer layer has a length that extends from the proximal end to the distal end of the carrier.
- 30 6. An implantable electrode array of claim 2 wherein the carrier and the outer layer are each formed from a biocompatible elastomeric material.
7. An implantable electrode array of claim 6 wherein the carrier is relatively  
35 more resiliently flexible in a longitudinal plane and relatively less resiliently flexible in a lateral plane.

8. An implantable electrode array of claim 7 wherein the carrier is relatively resiliently flexible such that it adopts the first configuration of the array determined by the adhesive layer prior to implantation and the second configuration determined by the preferred configuration of the outer layer following completion of the implantation procedure.
9. An implantable electrode array of claim 7 wherein the first configuration is at least substantially straight and the second configuration is at least substantially spirally curved.
10. An implantable electrode array of claim 9 wherein, following completion of implantation, the second spirally curved configuration results in the carrier being positioned within the cochlea of the implantee with said surfaces of the electrodes being oriented to face the modiolus of the cochlea.
11. An implantable electrode array of claim 10 wherein the adhesive layer is formed from a bioresorbable material that softens or dissolves on exposure to a body fluid of the implantee.
12. An implantable electrode array of claim 11 wherein, following implantation, the carrier subtends an angle of at least about 360°, and more preferably about 450°.
13. An implantable electrode array of claim 11 wherein the bioresorbable material of the adhesive layer is selected from the group consisting of polyacrylic acid (PAA), polyvinyl alcohol (PVA), polylactic acid (PLA) and polyglycolic acid (PGA).
14. An implantable electrode array of claim 11 wherein the distal end of the carrier is attached to the distal end of the outer layer by an attachment means other than the bioresorbable layer.
15. A method of forming an implantable electrode array that can adopt a first configuration selected to allow the array to be inserted into an implantee's body



and at least a second configuration wherein said electrode array is adapted to apply tissue stimulation, the method comprising the steps of:

- (i) moulding an elongate carrier in a substantially straight configuration in a first mould from a resiliently flexible material about a longitudinal array of electrodes such that at least one of the electrodes has a surface that is at least adjacent an inner surface of the carrier;
- (ii) separately moulding at least an outer layer of the array in a second mould from a resiliently flexible material, the outer layer being moulded in a curved configuration;
- (iii) removing the outer layer from the second mould, straightening the outer layer and adhering it to the carrier using a bioresorbable adhesive.

16. A method of forming an implantable electrode array of claim 15 wherein the array is insertable into a cochlea of an implantee.

17. A method of forming an implantable electrode array of claim 16 wherein the second mould used to mould the outer layer is spiral-shaped such that the outer layer, following its manufacture and removal from the second mould, subtends an arc of about 450° or greater.

18. A method of forming an implantable electrode array of claim 17 wherein once the outer layer is cured, it is removed from the second mould and straightened in a straightening jig.

19. A method of forming an implantable electrode array of claim 15 wherein once the outer layer is adhered to the carrier, the array formed by this process is removed from the first mould and packaged.

20. A method of inserting an implantable electrode array in a cochlea of an implantee comprising the steps of:

- (i) performing a cochleostomy;
- (ii) inserting the electrode array of claim 9 through the cochleostomy;
- (iii) closing the cochleostomy.

21. A method of inserting an implantable electrode array of claim 20 wherein during step (ii) the adhesive layer bonding the outer layer and carrier gradually

dissolves thereby allowing the outer layer to begin to move towards its second configuration and so pushing the resiliently flexible carrier closer to the inner wall of the cochlea.

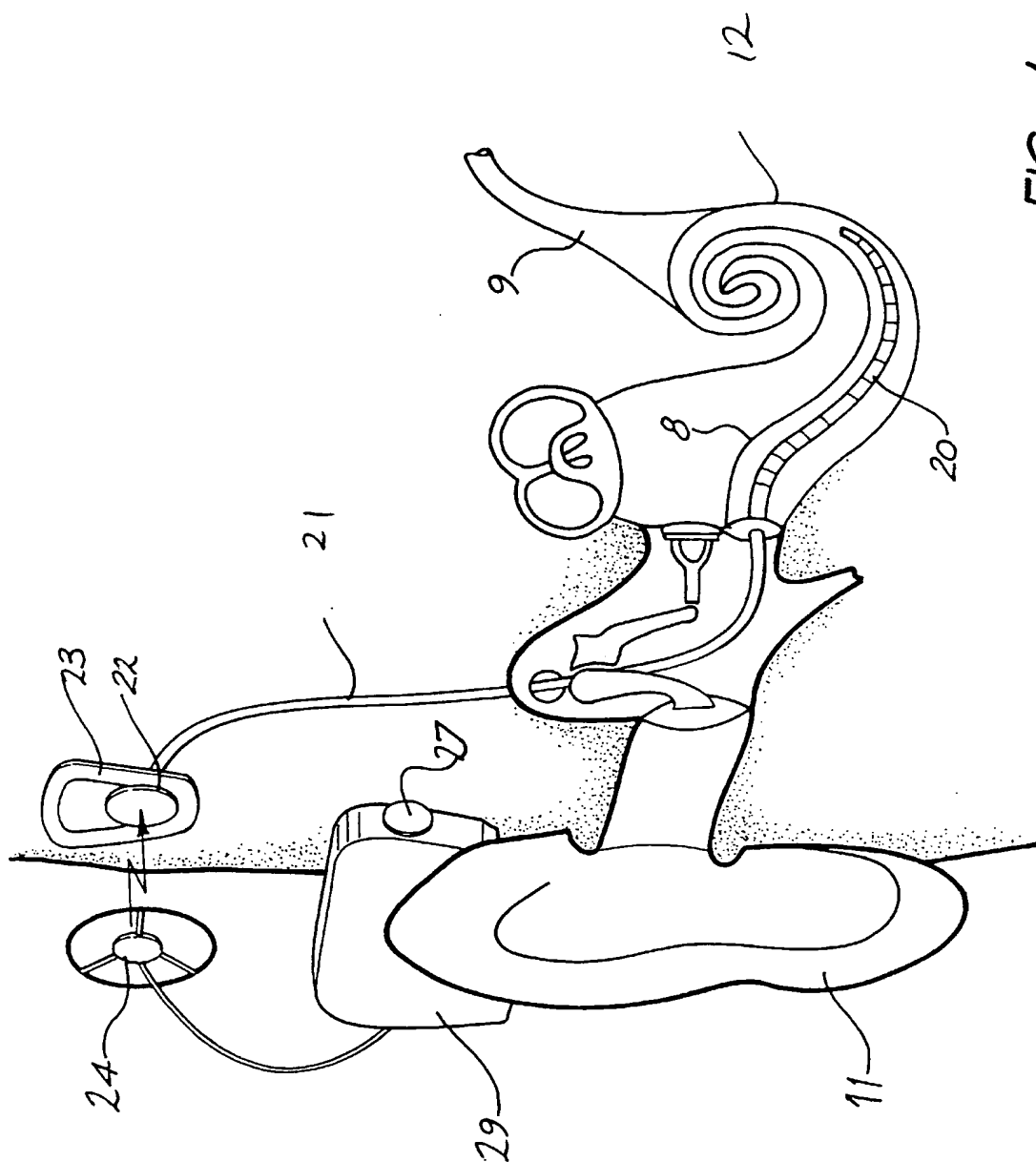
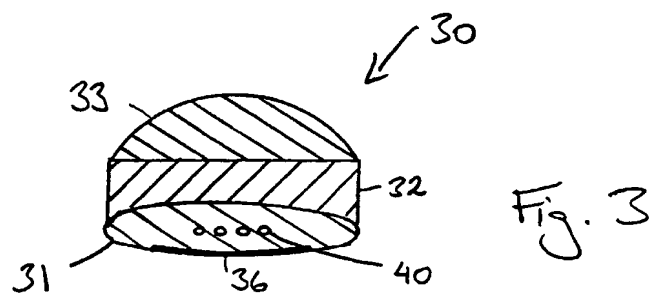
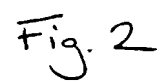
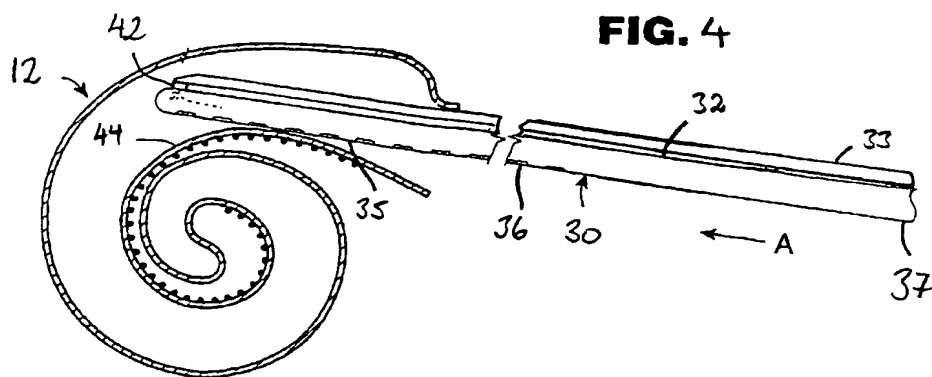


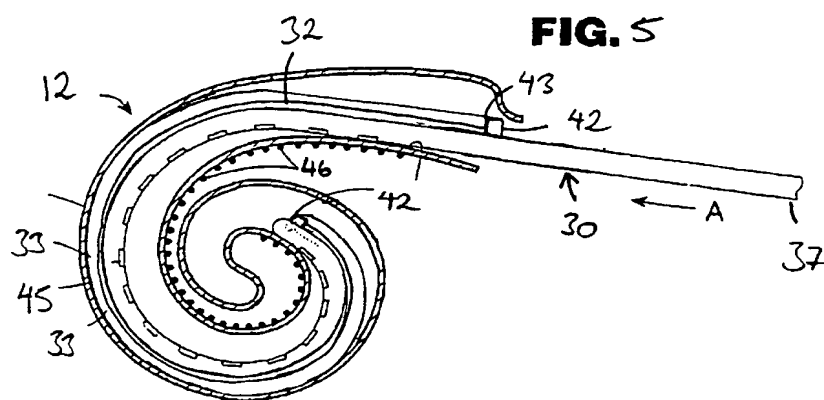
FIG. 1



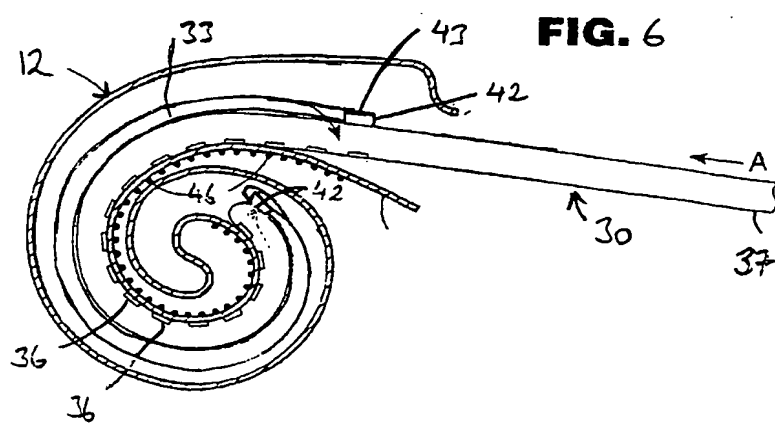
**FIG. 4**

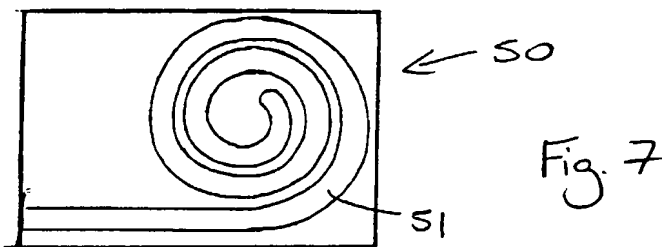


**FIG. 5**



**FIG. 6**





## INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU02/00272

|   |   |  |  |  |     |   |     |   |     |  |     |   |     |  |     |  |     |   |     |  |  |  |
|---|---|--|--|--|-----|---|-----|---|-----|--|-----|---|-----|--|-----|--|-----|---|-----|--|--|--|
| <b>A. CLASSIFICATION OF SUBJECT MATTER</b>  |   |  |  |  |     |   |     |   |     |  |     |   |     |  |     |  |     |   |     |  |  |  |
| Int. Cl. <sup>7</sup> : A61F 2/18, A61F 11/04, A61N 1/05, A61N1/36, H04R 25/00  |   |  |  |  |     |   |     |   |     |  |     |   |     |  |     |  |     |   |     |  |  |  |
| According to International Patent Classification (IPC) or to both national classification and IPC   |   |  |  |  |     |   |     |   |     |  |     |   |     |  |     |  |     |   |     |  |  |  |
| <b>B. FIELDS SEARCHED</b>   |   |  |  |  |     |   |     |   |     |  |     |   |     |  |     |  |     |   |     |  |  |  |
| Minimum documentation searched (classification system followed by classification symbols)   |   |  |  |  |     |   |     |   |     |  |     |   |     |  |     |  |     |   |     |  |  |  |
| Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched   |   |  |  |  |     |   |     |   |     |  |     |   |     |  |     |  |     |   |     |  |  |  |
| Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)<br>WPAT, INSPEC, INTERNET: implant, cochlear, electrode, array, layers, curved, conform, biocompatible, bioresorbable  |   |  |  |  |     |   |     |   |     |  |     |   |     |  |     |  |     |   |     |  |  |  |
| <b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>   |   |  |  |  |     |   |     |   |     |  |     |   |     |  |     |  |     |   |     |  |  |  |
| Category*   | Citation of document, with indication, where appropriate, of the relevant passages  | Relevant to claim No.  |  |  |     |   |     |   |     |  |     |   |     |  |     |  |     |   |     |  |  |  |
| X   | WO 93/06698 A1 (COCHLEAR PTY LTD) 1 April 1993<br>See page 2 line 30 to page 3 line 16.   | 1-11, 20, 21   |  |  |     |   |     |   |     |  |     |   |     |  |     |  |     |   |     |  |  |  |
| A   | WO 97/10784 A1 (COCHLEAR LTD) 27 March 1997<br>See the whole document   |  |  |  |     |   |     |   |     |  |     |   |     |  |     |  |     |   |     |  |  |  |
| A   | US 6038484 A (KUZMA) 14 March 2000<br>See the Abstract  |  |  |  |     |   |     |   |     |  |     |   |     |  |     |  |     |   |     |  |  |  |
| <input type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex  |   |  |  |  |     |   |     |   |     |  |     |   |     |  |     |  |     |   |     |  |  |  |
| <p>* Special categories of cited documents:</p> <table border="0"> <tr> <td>"A"</td> <td>document defining the general state of the art which is not considered to be of particular relevance</td> <td>"T"</td> <td>later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</td> </tr> <tr> <td>"E"</td> <td>earlier application or patent but published on or after the international filing date</td> <td>"X"</td> <td>document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</td> </tr> <tr> <td>"L"</td> <td>document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</td> <td>"Y"</td> <td>document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</td> </tr> <tr> <td>"O"</td> <td>document referring to an oral disclosure, use, exhibition or other means</td> <td>"&amp;"</td> <td>document member of the same patent family</td> </tr> <tr> <td>"P"</td> <td>document published prior to the international filing date but later than the priority date claimed</td> <td></td> <td></td> </tr> </table> |   |  | "A"  | document defining the general state of the art which is not considered to be of particular relevance | "T" | later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention | "E" | earlier application or patent but published on or after the international filing date | "X" | document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone | "L" | document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | "Y" | document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art | "O" | document referring to an oral disclosure, use, exhibition or other means | "&" | document member of the same patent family | "P" | document published prior to the international filing date but later than the priority date claimed |  |  |
| "A"   | document defining the general state of the art which is not considered to be of particular relevance  | "T"  | later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention  |  |     |   |     |   |     |  |     |   |     |  |     |  |     |   |     |  |  |  |
| "E"   | earlier application or patent but published on or after the international filing date   | "X"  | document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone   |  |     |   |     |   |     |  |     |   |     |  |     |  |     |   |     |  |  |  |
| "L"   | document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | "Y"  | document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |  |     |   |     |   |     |  |     |   |     |  |     |  |     |   |     |  |  |  |
| "O"   | document referring to an oral disclosure, use, exhibition or other means  | "&"  | document member of the same patent family  |  |     |   |     |   |     |  |     |   |     |  |     |  |     |   |     |  |  |  |
| "P"   | document published prior to the international filing date but later than the priority date claimed  |  |  |  |     |   |     |   |     |  |     |   |     |  |     |  |     |   |     |  |  |  |
| Date of the actual completion of the international search<br>5 April 2002   |   | Date of mailing of the international search report<br>15 APR 2002        |  |  |     |   |     |   |     |  |     |   |     |  |     |  |     |   |     |  |  |  |
| Name and mailing address of the ISA/AU<br>AUSTRALIAN PATENT OFFICE<br>PO BOX 200, WODEN ACT 2606, AUSTRALIA<br>E-mail address: pct@ipaustalia.gov.au<br>Facsimile No. (02) 6285 3929  |   | Authorized officer<br><br>Andrea Hadley<br>Telephone No : (02) 6283 2222 |  |  |     |   |     |   |     |  |     |   |     |  |     |  |     |   |     |  |  |  |

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International application No.  
**PCT/AU02/00272**

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

| Patent Document Cited in<br>Search Report |         | Patent Family Member |           |    |           |    |           |
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| WO  | 9306698 | AU                   | 26864/92  | EP | 724819    | US | 5578084   |
| WO  | 9710784 | AU                   | 35973/95  | CA | 2230595   | US | 5653742   |
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|   |         | WO                   | 9911321   | US | 6078841   | US | 6119044   |
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|   |         | US                   | 6163729   | US | 6195586   | US | 6304787   |
|   |         | US                   | 6309410   | US | 6321125   | AU | 43168/99  |
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|   |         | EP                   | 1173250   | WO | 200064529 | AU | 200048460 |
|   |         | EP                   | 1185332   | US | 6259951   | WO | 200069513 |
|   |         | AU                   | 200047129 | EP | 1185331   | WO | 200069512 |
| END OF ANNEX                              |         |                      |           |    |           |    |           |